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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/090,675   | 03/05/2002  | Andrew F. Phillips   | PHL-003                 | 8514             |
| 7590   | 03/17/2004  |                      | EXAMINER                |                  |
| David P. Gordon<br>65 Woods End Road<br>Stamford, CT 06905 |             |                      | MILLER, CHERYL L        |                  |
|  |             |                      | ART UNIT                | PAPER NUMBER     |
|  |             |                      | 3738                    |                  |
|  |             |                      | DATE MAILED: 03/17/2004 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

EG

|                              |                        |   |
|------------------------------|------------------------|---|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>                       |
|                              | 10/090,675             | PHILLIPS, ANDREW F.<br><i>[Signature]</i> |
|                              | <b>Examiner</b>        | <b>Art Unit</b>                           |
|                              | Cheryl Miller          | 3738                                      |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 January 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.  
 4a) Of the above claim(s) 2-6, 8, 13-16, 19-21 and 23-32 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1, 7, 9, 10, 12, 18, 22, 33 and 34 is/are rejected.  
 7) Claim(s) 11 and 17 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

**DETAILED ACTION*****Response to Arguments***

Applicant's arguments with respect to claims 1, 7, 9-10, 12, 17-18, and 22 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson (USPN 5,607,472, cited by applicant in IDS). Referring to claim 1, Thompson discloses an IOL (22) comprising an optic portion (23) having a first flexibility, a peripheral portion (36) having a second flexibility less than the first (will be less flexible due to the presence of the viscoelastic material and the flap in this portion), and a restraining element (viscoelastic material) provided to the peripheral portion (36) and adapted to maintain the optic in a stressed state of a lower optical power (col.3, lines 3-15; col.5, lines 30-39; col.6, lines 15-28) relative to an accommodating non-stressed state, the restraining element (viscoelastic material) being removable (material is *removable*, that is, it is capable of being removed, and if removed, would provide the function claimed, it is noted to the applicant, that the language *removable* is functional, therefore given less patentable weight, stronger language would include

language such as, "wherein after implantation the restraining element is removed from the intraocular lens") without an invasive surgical procedure after completion of surgery (this is a method step within a product claim, and not given weight in a product claim, further, the element is still adapted to be removed non-invasively, for instance, by a small puncture, or high laser beam that cuts the surface of the periphery), wherein upon removal of the restraining element (if the element, viscoelastic material, were removed), the optic portion (23) is biased toward the accommodating non-stressed state (injection of the restraining element, viscoelastic material in this case, put the optic in a stressed state, therefore, if the restraining element were to be removed, the optic would return to its original non-stressed state, and actually does so anyway, upon implantation by the action of the ciliary muscles, even without removal) in which the optic portion (23) has increased optical power, and wherein the optical power of the optic portion is adjustable in response to stresses induced by the eye (accommodates after implantation, col.1, lines 6-9; col.6, lines 42-50).

Referring to claim 7, Thompson discloses a peripheral portion (36) including a channel (28), the restraining element (viscoelastic material) including a fluid placed within the channel (28), the channel including an outlet (29) having a seal (32) that prevents fluid from escaping, and the seal (32) adapted to be opened in a non-surgically invasive manner (seal is *adapted* to be opened, it's a valve which opens and closes, further, non-surgically invasive manner is a method step).

Referring to claim 18, Thompson discloses a peripheral portion (36) including a structure (37, 38) adapted to promote tissue attachment (flaps and adhesive will attach to tissue, col.3, lines 28-40; col.6, lines 33-42).

Claims 1, 18, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Donnell, Jr. (USPN 5,549,668, cited in previous office action). See figures 5, 6, and respective portions of the specification. Referring to claim 1, O'Donnell discloses an IOL (1) comprising an optic portion (14) having a first flexibility (col.5, lines 15-17), a peripheral portion (12, 13) having a second flexibility less than the first, and a restraining element (15) provided to the peripheral portion (see fig.5, 6) and adapted to maintain the optic (14) in a stressed state at a lower optical power, the restraining element being removable (restraining element is disclosed to be hydrogel or collagen, collagen which will dissolve over time, will be removable, and either one, with a high enough laser beam, could be removed, therefore, the element is *removable*, since applicant has not positively claimed the element to be removed or not present in the lens after implantation) without an invasive procedure after completion of the eye surgery, wherein upon removal of the restraining element, the optic is biased toward the accommodating non-stressed state with an increased optical power (col.3, lines 13-19), and wherein the optical power of the optic portion is adjustable in response to stresses induced by the eye (the structure of O'Donnell's lens when placed in the capsular bag would allow it to accommodate, by forward and backward movement of the optic).

Referring to claim 18, O'Donnell discloses a peripheral portion (12, 13) including a structure adapted to promote tissue attachment (distal end of haptics 12, 13 will contact the walls of the capsule and the tissue will attach and grow around them).

Referring to claims 33 and 34, O'Donnell discloses a restraining element (15) removable without physical contact by a laser beam (element is *removable*, that is, the element is capable of

being removed, such as by a stronger laser, or longer duration of laser treatment, or different type of laser).

Claims 1, 7, 9, 10, 12, 18, 22, 33, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Shadduck (Pub. No. US 2003/0060878 A1). See embodiment in figure 10.

Referring to claim 1, Shadduck discloses an IOL (100) comprising an optic portion (125) having a first flexibility, a peripheral portion (outer circumference, 126) about the optic portion having a second flexibility less than the first (will have a different flexibility due to the presence of an additional material), and a restraining element (fluid media M) provided to the peripheral portion (126) and adapted to maintain the optic portion in a stressed state of a lower optical power [0039] relative to an accommodating non-stressed state, the restraining element being removable (the restraining element, fluid media M, is removed from the peripheral portion 126, therefore, it is removed) without an invasive surgical procedure after completion of eye surgery (the removal of the element from the peripheral portion is non-invasive, further this is a method step in a product claim and not given as much weight), wherein upon removal of the restraining element (once the fluid is removed from the peripheral portion into the optical portion), the optic portion is biased toward the accommodating non-stressed state in which the optic portion has increased optical power [0039, 0045], and wherein the optical power of the optic portion is adjustable in response to stresses induced by the eye (although the lens is not disclosed to be placed in the capsular bag, if it were placed there, it would accommodate, due to its structure and flexibility).

Referring to claim 7, Shadduck discloses a peripheral portion (126) including a channel (155B), the restraining element (fluid media M) including a fluid placed within the channel, the

channel (155B) including an outlet (holes in porous wall 160) having a seal (initial nonporous structure of 160, see [0045]) that prevents the fluid from escaping the channel (155B), the seal (160) adapted to be opened in a non-surgically invasive manner [0045].

Referring to claim 9, Shadduck discloses a seal (initial nonporous structure of 160, seal being the closed pores) comprising a material removable upon the application of laser light [0045].

Referring to claim 10, Shadduck discloses an outlet (holes in 160) including a tubular element (at pore is a tubular element extending from the channel to the optic) extending toward the optic portion.

Referring to claim 12, Shadduck discloses a fluid to be a salt balanced solution (saline solution [0038]).

Referring to 18, Shadduck discloses a peripheral portion (126) including structure adapted to promote tissue attachment (tissue will attach to haptics 112 surrounding 126).

Referring to claims 33-44, Shadduck discloses a restraining element removable without physical contact, with a laser beam (fluid is removable, from the peripheral portion, by the laser when it opens up 160, [0045]).

Referring to claim 22, Shadduck discloses an IOL (100) comprising an optic portion (125) having a first flexibility, a peripheral portion (126) having a second flexibility less than the first, a restraining element (fluid media M) provided to the peripheral portion in a restraining configuration, wherein the optic portion is in a stressed state, and a dissolvable or laser-removable element (160) which upon dissolution or removal releases the restraining element (fluid media M) from the restraining configuration (moves from peripheral portion to the optic

portion) and permits the optic portion to enter an accommodating state in which the optic portion increases its optical power [0039, 0045], and wherein the optical power of the optic portion is adjustable in response to stresses induced by the eye (although the lens is not disclosed to be placed in the capsular bag, if it were placed there, it would accommodate, due to its structure and flexibility).

Claims 1, 18, 22, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (USPN 4,575,373). Referring to claim 1, Johnson discloses an IOL (1) comprising an optic portion (8) having a first flexibility (col.3, lines 40-46), a peripheral portion (2) about the optic portion having a second flexibility less than the first (rigid), and a restraining element (4) provided to the peripheral portion (2) and adapted to maintain the optic portion in a stressed state of a lower optical power relative to an accommodating non-stressed state, the restraining element being removable without an invasive surgical procedure after completion of eye surgery , wherein upon removal of the restraining element, the optic portion is biased toward the accommodating non-stressed state in which the optic portion has increased optical power (col.4, lines 7-14), and wherein the optical power of the optic portion is adjustable in response to stresses induced by the eye (if IOL 1 is placed in the capsular bag, it will accommodate due to its structure and flexibility, especially since the optic is adjustable, col.3, lines 40-46).

Referring to 18, Johnson discloses a peripheral portion (2) including structure adapted to promote tissue attachment (col.3, lines 30-31).

Referring to claims 33-44, Johnson discloses a restraining element (4) removable without physical contact, with a laser beam (col.4, lines 7-14).

Referring to claim 22, Johnson discloses an IOL (1) comprising an optic portion (8) having a first flexibility (col.3, lines 40-46), a peripheral portion (2) having a second flexibility less than the first (rigid, col.3, lines 27-28), a restraining element (4) provided to the peripheral portion (2) in a restraining configuration (fig.1, 2), wherein the optic portion is in a stressed state, and a dissolvable or laser-removable element (parts of 4 only where 6 is located) which upon dissolution or removal releases the restraining element (4) from the restraining configuration and permits the optic portion to enter an accommodating state in which the optic portion increases its optical power (col.4, lines 7-14), and wherein the optical power of the optic portion is adjustable in response to stresses induced by the eye (the optic will inherently accommodate if placed in the capsular bag, due to its structure and flexibility, col.3, lines 40-46).

***Allowable Subject Matter***

Claims 11 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

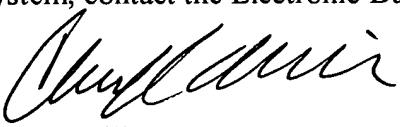
Art Unit: 3738

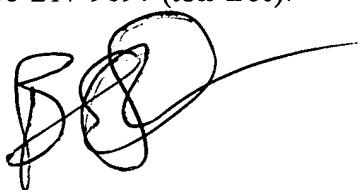
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Cheryl Miller



BRUCE SNOW  
PRIMARY EXAMINER